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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/308,407 07/08/99 KOCH

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EXAMINER

MIGGINS, M

ART UNIT

PAPER NUMBER

1772

DATE MAILED:

05/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/308,407

Applicant(s)
Koch et al.

Examiner
Mike Miggins

Group Art Unit
1772



☒ Responsive to communication(s) filed on 7/8/99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 9-17 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 9-17 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Specification

1. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- © Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 1. Field of the Invention.
 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (I) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 9-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is indefinite for containing the limitation "such as transdermal therapeutic systems", terms like "such as" are considered to be indefinite.

Claim 15 is indefinite for reciting the term "renders", it is unclear to one of ordinary skill in the art whether the heat sealing layer renders or comprises a chemical composition which is sufficiently inert to nicotine.

4. The term "sufficiently" in claim 15 is a relative term which renders the claim indefinite. The term "sufficiently" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 9-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardell (U.S. Patent No. 3,938,659) in view of Hunt et al. (U.S. Patent No. 5,077,104).

Wardell teaches a packaging system made of a composite packaging material for the sealed enclosure of products for pharmaceutical products comprising a heat sealing layer wherein the heat sealing layer is formed by an active ingredient-resistant, said active-ingredient resistant layer being applied from the liquid phase in a printing method and, after heat-activated sealing, displaying adhesion forces which are in the region of strength of the packaging materials and wherein the heat sealing layer covers only the sealing area (column 3, lines 1-68, column 4, lines 1-68, column 5, lines 1-20 and Fig. 2). Although Wardell does not specifically teach that the active ingredient-resistant layer has a thickness of maximally 15 g/m² or between 2.5 and 3.5 g/m², it would have been an obvious matter of design choice to fabricate an active ingredient-resistant layer has a thickness of maximally 15 g/m² or between 2.5 and 3.5 g/m², since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955) (applies to instant claims 9 and 11-12).

The difference between the instant claims and Wardell is that Wardell does not teach a packaging system for pharmaceuticals comprising a barrier layer on the product side to which barrier layer there is applied a heat sealing layer and wherein the barrier layer comprises aluminum.

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Hunt et al. teach a packaging system for pharmaceuticals comprising a barrier layer on the product side to which barrier layer there is applied a heat sealing layer and wherein the barrier layer comprises aluminum (abstract, column 2, lines 48-68, column 4, lines 48-68, column 5, lines 1-34 and Figs. 2-3 and 6-7) (applies to instant claims 9 and 14).

One of ordinary skill in the art would have been motivated to combine the teachings of Wardell and Hunt et al. because both references teach a packaging system for pharmaceuticals sealed by heat sealing and Hunt et al. provides a barrier which prevents the degradation of pharmaceuticals.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the packaging system of Wardell by fabricating a packaging system comprising a barrier layer on the product side to which barrier layer there is applied a heat sealing layer and wherein the barrier layer comprises aluminum according to the teachings of Hunt et al. because by fabricating such a packaging system, a packaging system which prevents the degradation of pharmaceuticals is obtained.

7. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardell (U.S. Patent No. 3,938,659) in view of Hunt et al. (U.S. Patent No. 5,077,104), as applied to claims 9-12 and 14, and further in view Flieger (U.S. Patent No. 5,447,772).

Hunt et al. teach a packaging system which is inert to nicotine (abstract, column 2, lines 48-68, column 4, lines 48-68, column 5, lines 1-34 and Figs. 2-3 and 6-7) (applies to instant claim 15).

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The difference between the instant claims and Wardell is that Wardell does not teach a packaging system wherein the heat sealing layer comprises an ethylene/methacrylic acid dispersion which displays no measurable active ingredient uptake and wherein heat sealing layer comprises a chemical composition which is sufficiently inert to nicotine.

Flieger teaches a packaging system wherein the heat sealing layer comprises an ethylene/methacrylic acid dispersion (column 2, lines 3-40) (applies to instant claim 13). Although Flieger does not specifically teach a packaging system wherein the heat sealing layer displays no measurable active ingredient uptake and wherein heat sealing layer comprises a chemical composition which is sufficiently inert to nicotine, it is the position that these properties are inherent in the heat sealing layer of Flieger because the heat sealing layer is made from the same material as that which is recited by the applicant in claim 13 (applies to instant claim 13 and 15).

One of ordinary skill in the art would have been motivated to combine the teachings of Wardell and Flieger because both references teach a packaging system comprising a heat sealing layer wherein the seal delaminates and Flieger teach a heat sealing layer with improved delaminating properties.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the packaging system of Wardell by fabricating a packaging system wherein the heat sealing layer comprises an ethylene/methacrylic acid dispersion which displays no measurable active ingredient uptake and wherein heat sealing layer comprises a chemical

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composition which is sufficiently inert to nicotine according to the teachings of Flieger because by fabricating such a packaging system, a packaging with improved delaminating properties is obtained.

8. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardell (U.S. Patent No. 3,938,659) in view of Hunt et al. (U.S. Patent No. 5,077,104), as applied to claims 9-12 and 14, and further in view of Wilking (U.S. Patent No. 5,698,217).

The difference between the instant claims and Wardell not yet discussed is that Wardell does not teach a packaging system comprising a layer within an area which is enclosed by the sealing layer, said enclosed layer entering into interaction with the packaged product and wherein the enclosed layer is formed by a moisture absorbent layer.

Wilking teaches a packaging system comprising a layer within an area which is enclosed by the sealing layer, said enclosed layer entering into interaction with the packaged product and wherein the enclosed layer is formed by a moisture absorbent layer (column 2, lines 1-67, column 5, lines 1-67 and Fig. 1) (applies to instant claims 16 and 17).

One of ordinary skill in the art would have been motivated to combine the teachings of Wardell and Wilking because both references teach a sealed packaging system for pharmaceuticals and Wilking provides a packaging system which prevents degradation of pharmaceuticals from moisture.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the packaging system of Wardell by fabricating a packaging system

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comprising a layer within an area which is enclosed by the sealing layer, said enclosed layer entering into interaction with the packaged product and wherein the enclosed layer is formed by a moisture absorbent layer according to the teachings of Wilking because by fabricating such a packaging system, a packaging system which prevents degradation of pharmaceuticals from moisture is obtained.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kwiatek et al. (U.S. Patent No. 4,573,996), Hsu et al. (U.S. Patent No. 4,700,531), Bayer et al. (U.S. Patent No. 4,956,181), Allen et al. (U.S. Patent No. 5,567,489) and Koch et al. (U.S. Patent No. 6,054,196) are cited as relevant prior art.

Any inquiry concerning this communication should be directed to Mike Miggins whose telephone number is (703)305-0915. The examiner can normally be reached Monday to Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ellis Robinson, can be reached on (703)308-2364. The fax phone number for the organization where this application or proceeding is assigned is (703)305-3599.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

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Ellis P. Robinson

**Ellis Robinson
Supervisory Patent Examiner
Technology Center 1700**

MCM *hcl*

5/21/00